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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,128	12/24/2003	John C. Reed	66821-0058	1734
41552	7590	08/24/2006		
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			EXAMINER AUDET, MAURY A	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/748,128

Applicant(s)

REED ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 8-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-7 is/are rejected.
- 7) ☒ Claim(s) 2-7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/01/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-5 and 28-33, as drawn to the elected core structure of TPI 927, in the reply filed on 06/01/2006 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to also search Group II, claims 6-7, drawn to a complex of IAP bound to the elected core structure TPI 927. Applicant's argument is found persuasive, and Group II, claims 6-7 are hereby rejoined.

Claims 1 and 8-68 are withdrawn as being drawn to non-elected subject matter. Additionally, the quote core structures of Figure 6, number 25 (proline), 73 (proline), 86 (aCIZ-Lys(eBoc)), and 88 ((aCBZ-Om(dBoc)); are withdrawn as not containing the same core with the formula for TPI 927 (top of Figures 6 and 9). Claims 2-7 are examined on the merits as drawn to the elected core structure TPI 927.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

The disclosure is objected to because of the following informalities:

1) Drawing Figures 6 and 9 and thus specification pages 5-6 are either not consistent or are duplicative internally or therebetween. See e.g. Figure 6, wherein the same #'s 91 and 103, is given to two structurally distinct R2 groups.

2) Additionally, as noted above, compound #'s 25, 73, 86, and 88 do not contain a substantial core with the TPI 927 formula at the top of Figures 6 and 9. It is suggested that these be put into their own separate Figure, distinct from the core compounds of TPI 927. They

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constitute a separate and distinct search, which is not coextensive with identified formula of elected TPI 927.

3) Also, under R1-R3 respectively, the structures are not in chronological order, which would help in accessing the Figure's more readily and it is suggested that Applicant apply a chronological order (while removing duplicates in each Figure).

Appropriate correction is required.

### ***Claim Objections***

Claims 2-7 are objected to because of the following informalities: the claims have not been amended to be commensurate in scope with the elected invention, namely core structures of TPI 927 and complexes if IAP bound thereto. Appropriate correction is required.

Claims 2-7 are objected to because of the following informalities: the term IAP in claims 2 and 6-7 and XIAP in claims 3-4 and 7 are not initially identified by their full name. Additionally, it is not known what all compounds stem from said IAP or XIAP, and Applicant is requested to expressly these, if there are a reasonable number (e.g. under 10, unless clearly defined in the specification, to which Applicant should so indicate as well). Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being obvious over Nefzi et al. (Tetrahedron Letters (2000), 41(29), 5441-5446).

Nefzi et al. teach an efficient two-step synthesis of mono-, di-, and triureas from resin-bound amides, which bear very close (if not express) limitations with the core structure options to that of elected TPI 927.

If not intrinsic therein, it would have been obvious to one of ordinary skill in the art at the time of the invention to arrive at one or more of the TPI 927 core structures in Nefzi et al., because Nefzi et al. advantageously teach compounds bearing at least the core formula of TPI 927 (if not some of the R1-R3 alternatives thereto).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

[The applied reference has common inventors (Nefzi and Houghten) and with the instant application. However, based upon the earlier effective U.S. filing date of the reference, it

constitutes prior art under 35 U.S.C. 102(b); therefore the options under other sections of 102 are not deemed available.]

***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Namely, the claims are drawn to core structures of TPI 927 (in e.g. Figure 9). However, as indicated above, structure #'s 25, 73, 86 and 88 are not core to the formula of TPI 927. Therefore, the Figures and claims are indefinite as to what structures actually fall within this core structure of TPI 927. As noted above, it is suggested that Applicant create a separate Figure to include structure #'s 25, 73, 86, and 88. Additionally (or alternatively), Applicant is required to expressly claim the core formula of TPI 927 and expressly claim the different R1-R3 groups which may stem therefrom. The compounds are not so numerous or large as to pose a burden on Applicant to expressly claim the same, and reference to Figures or lexicography type name (TPI 927) for actual structures are not to be used for the sake of convenience where such may be expressly and definitely claimed for clarity.

***Conclusion***

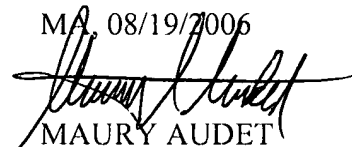
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 08/19/2006

  
MAURY AUDET  
PATENT EXAMINER  
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